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MEMORANDUM

SUBJECT: ***DIURON*** **-** Report of the FQPA Safety Factor Committee

FROM: Brenda Tarplee, Executive Secretary
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THROUGH: Ed Zager, Chairman
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PC Code: 035505

The FQPA Safety Factor Committee evaluated the available hazard and exposure data for Diuron on June 18, 2001 and recommended the FQPA safety factor to be used in human health risk assessments (as required by Food Quality Protection Act of August 3, 1996). The committee concluded that the FQPA safety factor could be removed (1x) in assessing the risk posed by this chemical.

I. HAZARD ASSESSMENT

(*Correspondence:* Y. Yang to B. Tarplee dated 06/06/01)

A. Adequacy of the Toxicology Database

There are acceptable studies in developmental toxicity study in rabbits and a two-generation reproduction study in rats. A developmental toxicity study in rats was classified as unacceptable due to deficiencies in analytical data on sample analysis; however, the HIARC considered the developmental toxicity study in rats is adequate for FQPA susceptibility assessment based on the NOAEL of developmental toxicity was higher than the maternal NOAEL. The HIARC concluded that a developmental neurotoxicity study with Diuron is not required.

B. Determination of Susceptibility

There is no indication of increased susceptibility to young exposed to Diuron in the available studies. In the developmental toxicity study in rabbits, there were no developmental effects at the highest dose tested. In the developmental toxicity study in rabbits and in the 2-generation rat reproduction study, developmental / offspring effects were observed only at a maternally / parentally toxic dose levels.

II. EXPOSURE ASSESSMENTS

A. Dietary Food Exposure Considerations

(*Correspondence:* J. Punzi to B. Tarplee dated 06/12/01)

Diuron is a preplant, pre- or post-emergent herbicide, used on a variety of fruits, vegetables, nuts, and field crops. Tolerances are established for residues of Diuron in or on food commodities at level ranging from 0.1 ppm to 7 ppm (40CFR §180.106).

The HED Metabolism Assessment Review Committee (MARC) concluded that for tolerance expression and risk assessment purposes, the residues of concern in/on plants, livestock, and poultry are diuron and its metabolites convertible to 3,4-dichloroaniline (*Memorandum*: J. Punzi to Y. Donovan; dated July 17, 2001).

USDA Pesticide Data Program (PDP) monitoring data are available for Diuron, however, these data do not measure 3,4 DCA. Therefore only field trial data will be used for dietary risk assessment. Additionally, percent crop treated data are available from BEAD.

The HED Dietary Exposure Evaluation Model (DEEM™) will be used to assess the risk from chronic dietary exposure to residues in food resulting from the use of Diuron (no acute endpoint

was identified). This analysis could be refined using the available percent crop treated data and anticipated residues calculated from field trials.

The Committee recognizes that further refinement to the dietary food exposure analyses may be required as the risk assessment is developed. Therefore, provided the final dietary food exposure assessment does not underestimate the potential risk for infants and children, the safety factor recommendations of this Committee stand.

B. Dietary Drinking Water Exposure Considerations
(*Correspondence:* I. Abdel-Saheb to B. Tarplee dated 06/06/01)

The environmental fate database is adequate to characterize drinking water exposure for the parent compound. These data indicate that parent Diuron is persistent and mobile. The only significant degradate in the aerobic and anaerobic aquatic metabolism studies was mCPDMU. Diuron has the potential to leach to ground and to contaminate surface waters. The HED MARC concluded that for risk assessment purposes, the residue of concern in drinking water are parent, DCPMU, and MCPDMU. Based on a structural analogy to monuron, the MARC recommended that a separate cancer assessment be conducted for MCPDMU (*Memorandum*: J. Punzi to Y. Donovan; dated July 17, 2001).

EFED has limited monitoring data on the concentrations of Diuron in surface water. A study on the occurrence of cotton herbicides and insecticides in Playa lakes of the high plains of western Texas concluded that Diuron was the major pesticide detected in water samples collected from 32 lakes (USGS, 1992). According to EFED, even though the use of Diuron on cotton in this part of the state is an example of actual use area, the frequency of sampling and the length of sampling period were not enough to represent a good monitoring data to be used for a regulatory purposes.

EFED also has limited monitoring data on the concentrations of Diuron in groundwater. The USEPA Pesticides In Groundwater Database (1992) shows validated monitoring data for Diuron that are available for the states of California, Florida, Georgia, and Texas.

Screening models were used to determine estimated concentrations of Diuron in groundwater and surface water:

> The FQPA Index Reservoir Screening Tool (FIRST) model was used to estimate surface water concentrations of Diuron from the use on citrus.
>
> The SCI-GROW screening model was used to estimate groundwater concentrations of Diuron. The groundwater concentrations estimated from the modeling agree with limited existing groundwater monitoring data for these compounds.

The Committee recognizes that further refinement to the dietary drinking water exposure analyses may be required as the risk assessment is developed. Therefore, provided the final dietary drinking water exposure assessment includes all environmental degradates of toxicological concern and does not underestimate the potential risk for infants and children, the safety factor recommendations of this Committee stand.

C. Residential Exposure Considerations

(*Correspondence:* R. Sandvig to B. Tarplee dated 06/07/01)

Children could potentially be exposed to Diuron since it is used for weed control on and around gravel driveways, patios, and wood decks. It is also used in residential ornamental ponds.

There are no chemical specific exposure data for Diuron. The Pesticide Handler's Exposure Database (PHED) will be used along with the Outdoor Residential Exposure Task Force (ORETF) database and the Residential SOPs in assessing residential risks resulting from the use of Diuron.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

A. Recommendation of the Factor

The Committee recommended that the FQPA safety factor be **removed (1x).**

B. Rationale for Removing the FQPA Safety Factor

The Committee concluded that the safety factor could be removed for Diuron because:

1. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure;
2. A developmental neurotoxicity study (DNT) with Diuron is not required; and
3. The dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children.